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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,818	02/05/2001	Kaname Ishibashi	400684	5334

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WASHINGTON, DC 20005-3960

EXAMINER

WHISENANT, ETHAN C

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/26/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/775,818

**Applicant(s)**

ISHIBASHI ET AL.

**Examiner**

Ethan Whisenant, Ph.D.

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 9 and 10 is/are rejected.
- 7) ☒ Claim(s) 6 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

**1.** The applicant's Response (filed 30 May 02) to the Office Action has been entered. The applicant's response has been entered as paper no. 5. The claims pending in this application are **Claim(s) 1-10**. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

### 35 USC § 102

**2.** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

### CLAIM REJECTIONS UNDER 35 USC § 102

**3.** **Claim(s) 1** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Singer et al. [US Patent No. 5,728,527 (1998)].

**Claim 1** is drawn to a method comprising three steps for selectively separating live cells expressing a particular mRNA from cells which do not express said particular mRNA.

Singer et al. teach a method for selectively separating live cells expressing a particular mRNA from cells which do not express said particular mRNA comprising the three steps recited in Claim 1. See for example the claims and Column 2, lines 1-16.

**35 USC § 103**

- 4.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 5.** This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

**CLAIM REJECTIONS UNDER 35 USC § 103**

- 6.** **Claim(s) 2-4 5,7, 9 is/are** rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al. [US Patent No. 5,728,527 (1998)] as applied against Claims 1 above and further in view of Tsuji et al. [US Patent No. 5,776,782 (1998)].

Singer et al. teach all of the limitations of **Claim 2-4** except Singer et al. do not explicitly teach an embodiment wherein the probe is composed of two probes capable of FRET. However, Tsuji et al. do teach a probe composed of two probes capable of FRET as well as hybridization and detection in living cells following irradiation with irradiating light. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Singer et al. wherein the probe is like that taught by Tsuji et al. Absent an unexpected result, the substitution of one well known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.



Singer et al. teach all of the limitations of **Claim 5** except Singer et al. do not explicitly teach an embodiment wherein the target mRNA is an mRNA encoding a cytokine. However, Singer et al. do teach detecting and separating cells which express a differentially expressed mRNA from cells not expressing said mRNA. See for example, Claims 24-25. In addition, Tsuji et al. teach detecting DNA or RNA in living cells. Note for example Column 1, lines 15-26 wherein the authors teach in reference to FRET, "This method is especially useful for in vitro measurements of small quantities of substances and can be applied to analysis of genetic information to measure expression of genes and changes in the primary structure of DNA and RNA to a high degree of precision". Based on these teachings, and absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Singer et al. in view of Tsuji et al. wherein the probe for the target mRNA detected any known mRNA, including an known mRNA for a known cytokine, known to be differentially expressed.

As regards the limitations in **Claims 7 and 9**, based on these teachings, and absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Singer et al. in view of Tsuji et al. wherein the cell that was separated was one known to have differential expression of some mRNA. For example, TH1 cells and TH2 cells.

**7. Claim(s) 10 is/are** rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al. [US Patent No. 5,728,527 (1998)] in view of Tsuji et al. [US Patent No. 5,776,782 (1998)] as applied against Claims 1-5, 7 and 9 above and further in view of Sixou et al.(1994).

Singer et al. in view of Tsuji et al. as argued above teach all of the limitations of **Claim 10** except these authors do not teach oligo delivery by microinjection or electroporation or lipofection. However, Sixou et al. do teach oligonucleotide hybridizations utilizing FRET wherein the oligos are delivered via microinjection. Therefore, absent an unexpected result, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method suggested by Singer et al. in view of Tsuji et al. wherein the probes for the target mRNA are delivered via microinjection. Absent an unexpected result, the substitution of one well known oligonucleotide delivery method with a second well known oligo delivery method with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

**RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS**

- 8.** Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection.

**CLAIM OBJECTIONS**

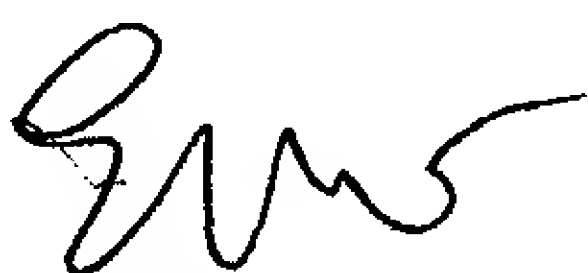
- 9.** Claim(s) 6 and 8 is /are objected to as being dependent upon a rejected base claim.

**CONCLUSION**

- 10.** Claim(s) 1-10 is/are rejected and/or objected to for the reason(s) set forth above.

- 11.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

  
**ETHAN C. WHISENANT**  
**PRIMARY EXAMINER**